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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/064,749
Filing Date: August 13, 2002
Appellant(s): DARROW ET AL.

General Electric Company
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/10/09 appealing from the Office action mailed 12/11/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,251,635	Dumoulin et al	10-1993
5,916,163	Panescu et al	06-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13-17, 19-22, and 30-31 have been rejected under 35 U.S.C. 112, first paragraph, as having failed to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *Claim 13 and the corresponding arguments of record with regard to claim 13 claim that the processor responds to change in the position of a medical device by **repositioning** the medical device within a target region of interest with moving the subject.* A thorough and complete search of Applicant's specification has provided no such teaching or capability of the processor element. Independent claims 1, 23 and 32 are not included in this rejection as they do not explicitly recite that the processor system itself repositions the medical device, rather that the system (or method) provides feedback (or is for) to **assist(ing)** in repositioning (emphasis added).

Claims 1, 2, 4-10, and 23-29 have been rejected under 35 U.S.C. 102(b) as having been anticipated by **Dumoulin et al. (U.S. Patent No. 5,251,635)**.

Regarding Claims 1, 7, and 23, Dumoulin et al. '635 teaches a medical device positioning system and method including a medical device adapted for internal use for performing the medical procedure, an imaging device (col. 1, lines 60-63), a medical device monitoring and positioning subsystem (col. 2, lines 2-10, 61-66, and 68) for monitoring the position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit and responding to motion of

at least one of the medical device or the subject in a predetermined fashion when the position of the medical device deviates from the target region of interest (col. 3, lines 1-4, 12-16 and 35-39), a tracking device, a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images, where the processor is further adapted to monitor a position of the medical device relative to the region of interest and to respond to changes in the position and provide feedback to an interface and where the operator initiates image acquisition at a selected location through an interface which is adapted to respond to the operator's input (col. 4, lines 16-19 and col. 7, lines 24-43).

Regarding Claims 2, 4-6, Dumoulin et al. '635 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device (col. 3, lines 1-4 and 22-25), that has a predetermined response of activating the imaging system to acquire a new image in response to the movement of the medical device relative to the target region within the subject, that provides advisory feedback to the interface unit when the medical device deviates from a target position (col. 4, lines 19-21, 25-35, 42-46 and 68), where the advisory feedback is a visual icon representing the position of the device (col. 5, line 1 and col. 7, lines 24-39).

Regarding Claims 8-10, and 26-29 Dumoulin et al. '635 teaches an imaging device that may be an MRI scanner, an X-ray device, a PET system, an ultrasound scanner or any other similar medical diagnostic imaging device, an invasive device that

may be at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser (col. 1, lines 60-63, col. 2, lines 25-28), an interface where the operator selects the desired position of the device and a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4, col. 4, lines 22-48) where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 7, lines 31-43 and 61-68 and col. 8, lines 1-3).

Claim 32 has been rejected under 35 U.S.C. 102(b) as having been anticipated by **Dumoulin et al. ('635)** or, in the alternative, under 35 U.S.C. 103(a) as having been found unpatentable over **Dumoulin et al. ('635)**.

Regarding Claims 24, 25, and 32, Dumoulin et al. disclose all that is listed above, and also discloses advisory feedback when the medical device deviates from a target position in the form of updating the image on the monitor or interface visual output of the system including the icon of the device and the region of interest (Col 3 Line 25-Col 4 Line 50 and Col 7 Line 24-47). While this embodiment does not explicitly disclose providing a *text advisory*, the monitor is *capable of displaying text and images*. In the alternative, it would have been obvious to one skilled in the art to modify the advisory from *image feedback* including displayed coordinate data (Col 4 Line 17-20) as taught by Dumoulin et al. to *text feedback* as an alternative functional equivalent to produce feedback to the operator in lieu of constantly updated images provides feedback to the

user in a predetermined fashion that allows for the user to choose to terminate therapy, continue with therapy, move the device without moving the patient, or any other response that someone skilled in the art would reasonably provide (Col 4 Line 17-20, Col 5).

Claims 11, and 12 have been rejected under 35 U.S.C. 103(a) as having been found unpatentable over **Dumoulin et al. '635**, in view of **Panescu et al (5,916,163)**. Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. in order to provide the operator with improved orientation of the

device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

(10) Response to Argument

Appellant's arguments with respect to claims 1, 2, 4-17, and 19-32 have been considered but are not persuasive.

In response to Appellant's arguments levied against the 102(b) and 103(a) rejections, that the references fail to show certain features of Appellant's invention, it is noted that some of the features upon which Appellant relies upon in arguments pertaining to the claims are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification or dependent claims are not read into the independent claims. See *In re Van Geuns*, 988 F.2d 1181, 26, USPQ2d 1057 (Fed. Cir. 1993).

With respect to Appellant's argument (A) corresponding to claim 13 and its dependent claims, Examiner respectfully disagrees that one of ordinary skill in the art would interpret the claim as written to imply anything other than it is a function of the processor to **reposition** the object in the area of interest. Within the art there exists a multitude of systems which are fully capable of automatic repositioning, either through magnetic actuation or other signal transmission whereby a processor actually performs the act of repositioning an instrument or other element within the body. The disclosure of [0025] of Appellant's specification does not cite that the processor repositions anything within the body, rather the processor "guides" or is "for" or "assists" in the placement or repositioning of an instrument. Examiner has stated that the feedback

system of the Instant Appeal provides for “feedback” “guidance” or “assistance” in repositioning, but does not actually perform **repositioning** itself, and as such this rejection should be upheld.

With respect to Appellant's argument (B) corresponding to claims 1 and 23, Examiner respectfully disagrees with the assertion that Dumoulin et al does not disclose a positioning system for repositioning a medical device within a target region without moving a subject when a position of the medical device deviates from a target area within the subject. Dumoulin et al discloses repeatedly imaging the anatomy and projecting the location of an invasive device so as to allow an operator to reposition said device within the body (Figure 1 and Col 7 Line 38 - 65, in particular Lines 59-65). Appellant has argued that the support arm moves the patient within the region of interest, but what is really occurring is the support arm is moving the patient to allow for acquisition of X-ray images to track the **medical device** (Col 7 line 24-37). This is wholeheartedly different from the act of repositioning the medical device (in one case a catheter or endoscope, as according to claim 3 of Dumoulin et al) and producing images which allow for the position of the medical device to be monitored during a procedure (Claim 1, section “g”). A support arm of Dumoulin et al (Element 101 of Figure 1) provides for the movement of the table upon which the patient is resting (**Element 110**), being wholeheartedly different from the invasive device (**Element 120**), *Element 120 is of course the actual element being tracked during the procedure (emphasis added)*. The support arm cannot reposition the invasive device within the body, as the support arm only controls the table upon which the patient is resting (See Figure 1), the images

produced by Dumoulin et al allow for the operator to track the medical device within the region of interest and as shown in Figure 1 (the element being held by the operator), the medical device is repositioned by the operator using a guide wire or other control device attached to the catheter within the body. Appellant's second argument, namely that Dumoulin et al fails to teach "a text of audio advisory" (sic), Examiner respectfully notes that recitation of a text **or** audio advisory is not found within either claim 1 or 23 as currently Appealed.

With respect to Appellant's argument (C) corresponding to claim 32, Examiner respectfully disagrees with Appellant's position that Dumoulin et al fails to disclose a positioning system for repositioning a medical device within a target region without moving a subject. The arguments above with regard to argument (B) apply *mutadi mutandis* to claim 32.

With respect to Appellant's argument (D) corresponding to claims 24, 25 and 32, namely that Dumoulin et al fails to render obvious the activation of an audio or text advisory, Examiner respectfully disagrees that one of ordinary skill in the art would not glean the same information of an audio or text advisory, from an updated, superimposed image of both the device and X-ray of the anatomy. One of ordinary skill in the art, namely a medical practitioner or technician, provided an updated image complete with an indication of the position of a medical instrument and even display coordinates (Recited Col 4 Line 17-20) on a monitor, would certainly be able to tell if a device has moved based off of an updated visual signal displayed on a monitor, much as one of ordinary skill in the art would understand the anatomy as depicted in the

image itself. In Dumoulin et al, an updated image of the device as relates to the anatomy of the body is produced, and the position of the device is indicated upon this updated image, thus giving a medical practitioner an indication as to the position of the device within the body.

With respect to Appellant's argument (E) corresponding to claims 11 and 12, no further arguments have been set forth aside from the claims being non-obvious as depending from claim 1. Examiner therefore direction attention to the response to arguments with respect to claim 1 above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/JOEL M LAMPRECHT/

Examiner, Art Unit 3737

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/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

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